

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/062,954	LAMB, GREGORY BLAIR	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the paper filed May 25, 2004.
2. ☒ The allowed claim(s) is/are 9,21,22 and 24-30.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

## **DETAILED ACTION**

### ***Status of the Application***

1. Currently, claims 9, 21, 22, and 24-30 are pending in the application. The claims were rejected in the Final Action mailed on January 28, 2004. In an After-Final Amendment filed on May 25, 2004, the Applicants amended claims 9, 21, 24-27, 29, and 30; and cancelled claims 1-8, and 10-20.
2. It is noted that the Applicant has indicated that the Office agreed, during the interview of May 21, 2004, that "Agreement was reached to amend claim 9" to insert the language "directly and solely," and that "Agreement was also reached that the method of the present invention provides an unexpected beneficial result" over the prior art. However, while the Office did suggest the language and indicated that the insertion of the language into the claims, in combination with evidence of an unexpected result would likely bring the application into condition for allowance, the Office did not agree that such would be the case.
3. Claims 9, 21, 22, and 24-30 are allowed.

### ***Reasons for Allowance***

4. The following is an examiner's statement of reasons for allowance: While the Office believes that the claims are now in condition for allowance, the reason are limited to the fact that the claims have now been amended such that they require the administration of botulinum toxin "directly and solely" to the intrinsic muscles of a patient. While the art indicates that the toxin may be administered to any muscle causing pain, the art does not teach or suggest the specific

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administration of the toxin solely and directly to the intrinsic muscles for the treatment of spinal compression.

It is further noted that this amendment to the claims is the sole ground for allowance. The Declaration filed on May 25 2004, purporting to teach unexpected results is not found persuasive because the declaration provides no more than an unsupported assertion of such results, without any evidence.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Claim Objections***

5. **(Prior Objection-Withdrawn)** Claim 21 is objected to because of the following informalities: in the listing of potential disorders, a comma is required between the last and next to last members (before the "and" in line 3 of the claim). The rejection is withdrawn in view of the amendment to the claim

6. **(Prior Objection-Withdrawn)** Claim 29 was objected to because of the following informalities: there is no comma between the term "(FGF)" and the word "and" in line 5 of the claim. The rejection is withdrawn in view of the amendment to the claim.

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7. **(Prior Objection-Withdrawn)** Claim 30 was objected to because of the following informalities: there is no comma between the term “botulinum toxin” and the “and” in line 4 of the claim. The rejection is withdrawn in view of the amendment to the claim.

***Claim Rejections - 35 USC § 103***

8. **(Prior Rejections- Withdrawn)** In the prior action, claims 9, 21, 22, and 24-27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan (U.S. Patent 6,500,436), Aoki et al. (U.S. Patent 6,290,961), Share (U.S. Patent 3,903,301) and Borodic et al., (Drug Safety 11(3): 145-52); claims 26 and 27 were rejected over Donovan, Aoki, Borodic, Share, and further in view of Moyer et al. (WO 00/15245); claim 28 was rejected over Donovan, Aoki, Borodic, Share, and either of De Simone (U.S. Patent 6,037,373), or Ferree (U.S. Application Publication 2002/0032155); and claim 30 was rejected over Donovan, Aoki, Borodic, Share, and Yamada et al., U.S. Patent 5,054,486. These rejections are withdrawn in view of the amendment of claim 9 to insert the “directly and solely” language, and for the reasons indicated in the Reasons for Allowance provided above.

***Conclusion***

9. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.


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Bajek et al., Acta Med Okayama 54(6): 235-41; and Yoshihara et al., Spine, 26(6): 622-26. These references are relevant in that they demonstrate that the art was aware that the multifidus (indicated by the Applicant to be an intrinsic muscle) played a part in disc herniation, but did not teach or suggest the treatment of such disorders through causing release of these muscles.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
JAMES HOUSEL 6/13/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600